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November 6, 1999

Dockets Management Branch
The Food and Drug Administration
Department of Health and Human Services, Rm. 1-23
12420 Parklawn Dr.
Rockville, MD 20857

via fax: 301.827.6870

RE: Docket Number: 99P-1340/CP 1

Petition FDA to declare Calvin Klein's Eternity eau de parfum "misbranded"

To Whom It May Concern:

Perfumes contain hundreds of lipophilic solvents. When a lipophilic solvent is applied to the surface of the skin (or inhaled) it is absorbed into the bloodstream and carried into the brain, liver and kidneys, and stored in fatty tissues throughout the body. As far as perfumes are concerned, what goes on the skin goes through the skin. This is the reality of the situation.

It is only logical that perfumes and their transdermal "delivery system" should be subjected to the same rigorous testing and safety requirements that the FDA already applies to skin-patch drug delivery systems. Most of the drugs that the FDA tests for patch-delivery have already been approved for delivery into the body by other means, whereas perfume components have neither been investigated nor approved for delivery by *any* means. We don't even know their effects, much less what concentrations are building up in the body.

Also to be taken into account is the fact that the human respiratory system is an extremely efficient absorber of volatile organic compounds. Approximately 95 percent of the volatile organics that are inhaled are absorbed into the body.

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The use of perfume constitutes the delivery of harmful phthalates, phenols and potential hormone disrupters as well as dozens of sensitizing and/or hazardous organic solvents — all with unknown long-term effects — into persistent storage within organs and fat depots of the body. Undoubtedly some degree of neurotoxicity or poisoning is caused by perfume ingredients. Therefore perfumes (especially the modern designer perfumes) should be considered dangerous until proven safe.

It is time to go beyond ignorance and wishful thinking. The first step is to conduct tests to investigate the appearance of perfume components in blood and fatty tissue after skin and lung exposure. It is outrageous to not be carefully testing the effects of repeatedly dosing the body with a solution containing hundreds of organic solvents of unknown long-term effects — particularly in these times of increasing cancer rates. Grandfathering is no excuse for not doing these tests. Neither is the "self-regulation" of the perfume industry. Safety testing by vested interests is meaningless.

The fragrance industry has argued for years that levels are so low they don't matter. Well, let us do the experiments and see what the levels are and what damage those levels produce. Determine the reality of: 1) the residual concentration of perfume components; 2) the build-up of this concentration with repeated use; and 3) the long-term effects of these concentrations, with particular attention to increased risk of breast cancer in women who are regular users of perfumes.

Sincerely,

Richard H. Conrad, PhD Biochemist